

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Kitson

Application No.: 09/780,060

Filed: 2/9/2001

Title: Skin Treatment Compositions and  
Methods of Use

Attorney Docket No.: TDIG.P-001

Group Art Unit: 1616

Examiner: M. Lamm

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GROUP 1600

Assistant Commissioner for Patents

Washington, D.C. 20231

OFFICIAL

SUPPLEMENTAL RESPONSE AFTER FINAL

Dear Sir:

This is in response to the Advisory Action mailed November 12, 2002 for the above-captioned application. Reconsideration of the application in view of the remarks herein is respectfully requested.

This paper is filed within three months of the mailing date of the original office action. Therefore no fees are believed to be due. However, in the event an extension of time is required, one is hereby requested, and the Commissioner is authorized to charge applicable fees to Deposit Account No. 15-0610.

Claims 1-3, 6-9 and 14-21 stand rejected under 35 USC § 103 over Kawada et al. In the Advisory Action, the Examiner acknowledges that liquid crystals are not "crystalline" but argues that the compositions of Kawada would inherently crystallize because they contain the same components as the claims. During a telephone conference, the Examiner confirmed that the

I hereby certify that this paper and any attachments named herein are transmitted to the United States Patent and Trademark Office, Fax number: 703-872-9307 on November 21, 2002.

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November 21, 2002  
Date of Signature

particular examples considered to be of greatest relevance were Compositions 26 and 27 in Kawada. Applicants respectfully submit that the Examiner has failed to present a case of inherency, and that there is nothing about the Kawada reference which would lead a person skilled in the art to anticipate that the compositions disclosed therein would crystallize when applied to skin.

In assessing whether a composition inherently meets a limitation recited in a claim, in this case the formation of a crystalline phase, it should be remembered that "inherency is not established by 'probabilities or possibilities.' The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency." *Scaltech, Inc. v. Retec/Tetra, LLC.*, 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999). Here, the Examiner's only argument is that the compositions disclosed in Kawada contain the same lipids (presumably the sterol and the palmitic acid). Since these compositions contain other materials as well, however, one must ask whether these compositions are consistent with achieving crystallization.

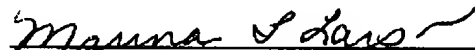
Compositions 26 and 27 of Kawada both contain cholesteryl sodium sulfate. The Examiner has not presented arguments that a salt of this type is consistent with crystallization occurring, and the inventors' research with this material shows that it does not crystallize to the same extent as cholesterol. Second, compositions 26 and 27 contain oleylamino-octadecane 1,3 diol. This compound has a cis-double bond in the chain (oleyl is 9,10 unsaturated). Lipids with this stereochemistry are sterically unlikely to crystallize (See page 5, ¶ 2). Finally, compositions 26 and 27 are said to be hydrated with a very small amount of water (200  $\mu$ l/20 g) and subjected to freeze thaw cycles. In contrast, the present invention is directed to aqueous formulations, and the lipid level in the aqueous buffer in example 1 is 8 mg/ml. Persons skilled in the art know that water and the pH and salt concentration of that water are important determinants in the phase behavior of lipids. Here, the exemplary material in the present application has 125,000 times more water than the hydrated lipids of the reference. The Examiner has not said why it would be reasonable to expect such different materials to act in the same way, and thus why it would be reasonable to expect that the Kawada compositions would crystallize.

In view of the foregoing, Applicants submit that the assertion of inherency is based on an overly simplistic interpretation of the Kawada reference and the very complex phase

change behavior of lipids. The person skilled in the art would not expect the Kawada formulations to crystallize. Thus, they do not suggest the presently claimed invention.

In view of the foregoing, Applicants submit that the application is in form for allowance. Favorable reconsideration is respectfully urged.

Respectfully Submitted,



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